From:	Christ, Lisa
To:	Ellis, Jerry; Hernandez-Quinones, Samuel
Subject:	FW: Material for 11/4 and 11/5 PAG briefings
Date:	Monday, November 03, 2014 9:34:08 AM
Attachments:	OW-OAR_PAG-brief_ 10312014_v1.docx PAGs 101 10-17-2014 v1.ppt Background on SDWA MCLs for Radionuclides.docx qrg_radionuclides.pdf OW Protocol August 2014 v 2.docx

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Hi Guys,
We need to send the materials to Ken according to the attached protocol. I sent a read ahead on the radionuclides rule to OARIA that may be a helpful reminder for Ken.
Thanks –
Lisa

From: Perrin, Alan
Sent: Friday, October 31, 2014 5:51 PM
To: OAR Briefings
Cc: Flynn, Mike; Burneson, Eric; Edwards, Jonathan; DeCair, Sara; Christ, Lisa; Veal, Lee; Cherepy, Andrea
Subject: Material for 11/4 and 11/5 PAG briefings

The attached material is for:

1) our internal DW PAG pre-brief with Janet McCabe (11/4 at 12:30 pm), and
2) the Janet McCabe/Ken Kopocis OW-OAR DW PAG briefing (12/5 at 4:30 pm).

Note that the attached "PAGs 101" file is a very short primer for background reading; the "OW-OAR PAG-brief" file will be the focus at the meetings. Please let me know if you have any questions. –Alan

Alan Perrin, Deputy Director
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Background on SDWA MCLs for Radionuclides:
In 1976 EPA issued interim regulations for Radionuclides in drinking water. In December 2000, EPA promulgated final regulations for four radionuclide groups:

- Gross Alpha (Minus Radon & Uranium) MCL = 15 pCi/L; Retained from 1976 Rule
- Combined Radium 226 & 228, MCL = 5 pCi/L; Retained from 1976 Rule
- Gross Beta & Photon, MCL = 4 mrem/yr (uses dose conversion factors from 1976 Rule); Retained from 1976 Rule
- Uranium MCL = 30 ug/L; Newly established standard

As a point of reference, for the gross beta & photon, MCL = 4 mrem annual dose:

- For Iodine-131 in drinking water the derived concentration corresponds to **3 pCi/L**
  - Based on limiting the dose to the thyroid to 4 mrem/yr
  - Assumes 70-year (lifetime) exposure through drinking water
  - Utilizes dose calculation methods developed in 1958 (ICRP 2)

- Current science (ICRP 72) would calculate the 4 mrem effective dose to the whole body, not a specific organ
  - **55 pCi/L for Children & 120 pCi/L for Adults for I-131**

Joint Briefing OW-OAR – Protective Action Guide (PAG) for Drinking Water

Purpose of this briefing:

- Present a recommendation for the Drinking Water PAG
- Discuss how we'll address the controversy associated with this proposal
- Agree on next steps toward publication for comment

What is the problem we're trying to solve?

- Drinking water is the only exposure pathway not currently addressed in the PAG Manual. At what radiation level does EPA recommend alternative drinking water resources be provided?
- Remember, a PAG is a health-based tipping point where actions are warranted to avoid a given radiation exposure.
- While highly unlikely, a large scale radiation contamination incident could impact the US, driving the need for a drinking water PAG that is pre-established and scientifically based.
- During the US response to the radiation incident at Fukushima, Japan in March 2011, rain water samples collected as part of RadNet showed concentrations of certain radionuclides above the SDWA Maximum Contaminant Levels (MCL).
- EPA experienced major difficulties conveying its message to the public that the detected levels in rain water, although greater than the MCL, were not of immediate concern to public health.
- If those same levels had been detected in drinking water, EPA may have had to issue ad-hoc guidance developed on short notice without the benefit of comprehensive analysis.

Options considered during PAG development:

a) Do nothing. Local governments or states may develop individual PAG levels, or EPA will need to create one after an incident occurs. Experience has shown that local governments often rely on EPA advice when making decisions regarding the safe use of drinking after contamination incidents. Radiation protection decisions are almost always based on federal guidance in some form. Affected federal entities (e.g., effected military personnel) will need federal guidance.

b) Use the SDWA MCL (4 mrem) as the level to provide an alternate source of drinking water. MCLs are not intended to inform 'do not drink' levels, in addition MCLs are based on the assumption of a 70 year exposure timeframe.

c) Adopt DHS & FDA benchmarks: 500 mrem from water for first year after an incident (DHS covers water after a terrorist attack and FDA guide applies to food). This allows for consistency with guidance that is already in use and publicly available.

d) Adapt above benchmarks that have long-standing acceptance, and add additional protection for pregnant women and children: 500 mrem for the general population and a lower dose level for children and pregnant women.

Recommendation:

- Based on an analysis of radiation risks to all age groups from several nuclides, we propose a two-tiered PAG as a reasonable approach considering age-based radiosensitivity.
- We recommend the drinking water PAG during the intermediate phase of a radiological response be 75 mrem projected dose in the first year for infants, children and pregnant women and 500 mrem projected dose in the first year for the general population.

The protective action:

- The protective action is to restrict the use of contaminated water for drinking purposes and to provide alternative drinking water for the affected community. Options for providing alternate drinking water could include: bottled water, altering the raw water source of a water system, interconnection between systems, or a combination of these.

Rationale:

- EPA conducted an assessment of the projected risks of excess cancer cases from exposure to radiation in drinking water at the 500 mrem level for a one year duration incident. The projected risks levels for adults at the 500 mrem level generally fall around the 0.0003 risk level for excess cancer cases.
- EPA conducted a similar assessment from exposure to contaminated drinking water for infants and children, who are more sensitive to radiation exposure, and found that the projected risk level of 0.0001 would occur at the 75 to 100 mrem dose level range.
- This recommended drinking water PAG approach is consistent with PAGs currently in place for other media. PAGs are set by balancing the risks of exposure to radiation against the logistical difficulty, costs and detriments associated with taking protective action to avoid exposure.
- According to the International Commission on Radiation Protection, emergency levels for protection of people should be selected in the lower part of the 100 to 2,000 mrem/year recommended range. Protection against all exposures, above or below the PAG level, should be balanced against detriments from the protective action itself.
- The government of Japan adopted a similarly tiered drinking water advisory when responding to the radiation incident in Fukushima.
- We determined that it is not appropriate to base emergency protective actions and response measures during short-term radiation incidents on lifetime (70 year) exposure criteria utilized to derive SDWA Maximum Contaminant Levels (MCL).
- We recognize that within the SDWA framework, water systems in violation of drinking water standards have processes available to get back into compliance within a reasonable time frame. While the SDWA framework is useful to inform actions for day-to-day normal operations, it does not provide adequate guidance for emergency responders on what levels of contamination warrant providing alternative water.
- We assume that any drinking water system adversely impacted during a radiation incident will be able to achieve compliance with MCLs within the first year after the incident.

Key considerations:

- Flexibility is emphasized. Emergency managers should make incident specific decisions that make sense for their community.
- Some PAGs lend themselves to age specificity (KI, food, water) while others are best applied to entire populations (sheltering, evacuation, and relocation). The goal is to protect everyone, including the most sensitive (children and pregnant women) while being practical with what may be limited alternative drinking water resources.
    - From a public information standpoint, the Manual may need to provide further information on the practical implementation challenges with a two tier water protection strategy. The KI simplified approach is an example of this.
- Pre-incident planning is encouraged. Pre-incident planning can help a community identify the best alternative water choices.

Stakeholder reaction:

- In response to a previous proposal, anti-nuclear and environmental groups publicized misleading comparisons of derived water PAG concentrations alongside MCL concentrations to assert that the SDWA was being weakened. This is likely to happen again.
- In addition, these groups had multiple meetings with then Assistant Administrator Gina McCarthy and Deputy Administrator Bob Perciasepe to voice their concerns about the drinking water PAG development.
- Stakeholders base their strong objections and opposition on the fact that exposure to drinking water with higher levels of radiation will likely result in an increased risk of cancer cases. The stakeholders go into detail pointing out the differences in concentration levels derived from a PAG of 500 mrem in comparison with an MCL of 4 mrem. For some radionuclides, the resulting difference in concentration could be up to several thousand times.
- During Fukushima, the Agency was pressed to develop drinking water guidance for US citizens in Japan and those using cisterns with contamination from the incident. The Agency failed to provide any guidance. Since then, both Bob and Gina have encouraged us to get this done.
- State radiation control programs, nuclear power plant response communities, and the American Water Works Association have asked EPA repeatedly for a drinking water PAG for emergencies. Comments submitted on our 2013 PAG Manual from many states, the AWWA, Health Physics Society, Nuclear Energy Institute and Conference of Radiation Control Program Directors specifically request a drinking water PAG.

Proposed next steps in the timeline:

November 2014: Joint AA-level briefing for OW and OAR (scheduled for Nov. 5)

December 2014 – January 2015: Brief multi-agency PAGs Subcommittee & get concurrence on proposal; concurrently have updated Water proposal reviewed by OSWER, OHS and OGC

February – March 2015: OW AA and OGC Review and Concurrence Process on drinking water PAG proposal and support documents

April 2015: Finalize drinking water PAG proposal *Federal Register* package

May 2015: OPEI review and facilitation

June 2015: Begin OMB 90-day review

Finalize edited FR Notice and Water proposal **(OMB release + 14 days)**

Complete *Federal Register* Workflow for Water proposal **(OMB release + 30 days)**

Public comment period **(OMB release + 90 days)**

Compile and adjudicate comments from public review **(OMB release + 120 days)**

Finalize entire PAG Manual including Water **(OMB release + 180 days = Jan 2016)**

EPA Protective Action Guides

PAGs 101

Promoting radiation safety worldwide.

Outline

- What is a PAG
- Who Uses PAGs
- Exposure Pathways
- Phases of Emergency Response
- Early, Intermediate & Late Phase PAGs
- Key Updates Issued in 2013

What is a PAG

- A projected dose to a defined individual from a release of radioactive material at which a specific protective action to reduce or avoid that dose is recommended
- Guidance for public officials
- Protective Action Guides are called 'PAGs'

For example:

- Scientists project a dose of 500 mrem in the first year.
- There is a protective action associated with that dose in the PAG Manual.
- Decision makers implement the recommended action as quickly as possible.
- The public actually receives a dose of 200 mrem.

Global PAGs, and Regulations

- All developed countries have PAGs in some form
  - ✓ The International Atomic Energy Agency provides high level guidelines which our federal guidance echoes
  - ✓ Radiation disasters are rare, but not 100% avoidable
  - ✓ The U.S. PAGs originated in 1960s in response to fallout from weapons testing
- Our public health and environmental regulations remain in effect, every day
  - ✓ Emergency guides are needed when a disaster takes us temporarily and unavoidably out of compliance

Who Uses the PAG Manual

- State and local emergency managers use EPA PAGs in local emergency response plans
- Nuclear power plant community decision makers
  - ✓ The same EPA PAG levels have been used for several decades around nuclear plants, for preparedness
  - ✓ Nuclear Regulatory Commission and FEMA require use of EPA PAGs in local emergency plans
- Urban areas with Homeland Security plans
  - ✓ EPA PAGs and the planning guidance are incorporated into local plans with assistance from FEMA and others

Phases of Response

- Early Phase: The first hours to days until the release has stopped, when protective actions decisions must be made with little to no information
- Intermediate Phase: The weeks to months when more information is available, protective actions are more restrictive, and cleanup planning begins
- Late Phase: No longer an emergency; activities shift to long term recovery and cleanup

Radiation Exposure Pathways

- The worst case scenario is a large release from a damaged nuclear power plant or a terrorist attack using radioactive material:
  - ✓ Airborne plume
  - ✓ Contamination on people
  - ✓ Ground and building contamination
  - ✓ Food and water contamination
  - ✓ Longer term spread into crops and the environment

Early Phase PAGs

- Evacuation/Shelter 1-5 rem (10-50 mSv); Provide KI 5 rem (50 mSv) child thyroid dose
  - ✓ These levels are used as health-based tipping points at which an action would be warranted. Predictions of dose based on the release or measurements must be compared to these tipping points to determine if prompt action is needed.
- Worker 5, 10, 25+ rem (50, 100, 250+ mSv)
  - ✓ These worker guides are more like limits. They guide stopping work if doses received meet these levels, based on how critical the work is (e.g., lifesaving)

Intermediate Phase PAGs

- Relocate population
  - ✓ ≥ 2 rem (20 mSv) first year (projected dose)
  - ✓ 0.5 rem (5 mSv) any subsequent year
- Apply dose reduction techniques
  - ✓ < 2 rem (20 mSv)
  - ✓ These PAGs are lower, and based on longer-term dose projections (first and second year)
- Food (FDA 1998): Most limiting of
  - ✓ 0.5 rem (5 mSv) whole body or
  - ✓ 5 rem (50 mSv) to most exposed organ or tissue

Late Phase

- Actions designed to reduce radiation levels in the environment begin
- Actions are meant to reduce long-term exposures and improve living conditions.
  - ✓ A PAG level, or numeric dose to avoid, is not appropriate for long-term cleanup
  - ✓ The PAG Manual describes a process involving stakeholders in decision making on clean-up goals, technology, land use and approaches
- Community involvement is key

2013 Revised PAG Manual

- Update to the 1992 PAG Manual
  - ✓ Expanded scope to include terrorism: RDD, IND
  - ✓ Incorporated updated FDA Potassium Iodide guidance
  - ✓ Refers to updated FDA Food guidance
  - ✓ Includes a new matrix on re-entry decisions
  - ✓ Provides brief cleanup and waste management planning guidance
  - ✓ Incorporates DHS 2008 late phase cleanup guidance
  - ✓ Updates science basis to updated international guides

Wrap Up

- Questions?
- Comments?
- Suggestions?

EPA
United States
Environmental Protection
Agency

Radionuclides Rule: A Quick Reference Guide

Overview of the Rule

Title*	Radionuclides Rule 66 FR 76708 December 7, 2000 Vol. 65, No. 236
Purpose	Reducing the exposure to radionuclides in drinking water will reduce the risk of cancer. This rule will also improve public health protection by reducing exposure to all radionuclides.
General Description	The rule retains the existing MCLs for combined radium-226 and radium-228, gross alpha particle radioactivity, and beta particle and photon activity. The rule regulates uranium for the first time.
Utilities Covered	Community water systems, all size categories.

*This document provides a summary of federal drinking water requirements; to ensure full compliance, please consult the federal regulations at 40 CFR 141 and any approved state requirements.

Public Health Benefits

Implementation of the Radionuclides Rule will result in . . .	Reduced uranium exposure for 620,000 persons, protection from toxic kidney effects of uranium, and a reduced risk of cancer.
Estimated impacts of the Radionuclides Rule include . . .	Annual compliance costs of $81 million. Only 795 systems will have to install treatment.

Regulated Contaminants

Regulated Radionuclide	MCL	MCLG
Beta/photon emitters**	4mrem/yr	0
Gross alpha particle	15 pCi/L	0
Combined radium-226/228	5 pCi/L	0
Uranium	30µg/L	0

**A total of 168 individual beta particle and photon emitters may be used to calculate compliance with the MCL.

Critical Deadlines & Requirements

For Drinking Water Systems	
June 2000 - December 8, 2003	When allowed by the State, data collected between these dates may be eligible for use as grandfathered data (excluding beta particle and photon emitters).
December 8, 2003	Systems begin initial monitoring under State-specified monitoring plan unless the State permits use of grandfathered data.
December 31, 2007	All systems must complete initial monitoring.
For States	
December 2000 - December 2003	States work with systems to establish monitoring schedules.
December 8, 2000	States should begin to update vulnerability assessments for beta photon and particle emitters and notify systems of monitoring requirements.
Spring 2001	EPA meets and works with States to explain new rules and requirements and to initiate adoption and implementation activities.
December 8, 2002	State submits primacy revision application to EPA. (EPA approves within 90 days.)

Monitoring Requirements

Gross Alpha, Combined Radium-226/228, and Uranium (1)	Beta Particle and Photon Radioactivity (1)
Initial Monitoring	
Four consecutive quarters of monitoring.	No monitoring required for most CWSs. Vulnerable CWSs (2) must sample for: • Gross beta: quarterly samples. • Tritium and Strontium-90: annual samples.
Reduced Monitoring	
If the average of the initial monitoring results for each contaminant is below the detection limit: One sample every 9 years. If the average of the initial monitoring results for each contaminant is greater than or equal to the detection limit, but less than or equal to one-half the MCL: One sample every 6 years. If the average of the initial monitoring results for each contaminant is greater than one-half the MCL, but less than or equal to the MCL: One sample every 3 years.	If the running annual average of the gross beta particle activity minus the naturally occurring potassium-40 activity is less than or equal to 50 pCi/L: One sample every 3 years.
Increased Monitoring	
A system with an entry point result above the MCL must return to quarterly sampling until 4 consecutive quarterly samples are below the MCL.	If gross beta particle activity minus the naturally occurring potassium-40 activity exceeds 50 pCi/L, the system must: • Speciate as required by the State. • Sample at the initial monitoring frequency.

(1) All samples must be collected at each entry point to the distribution system.
(2) The rule also contains requirements for CWSs using waters contaminated by effluents from nuclear facilities.

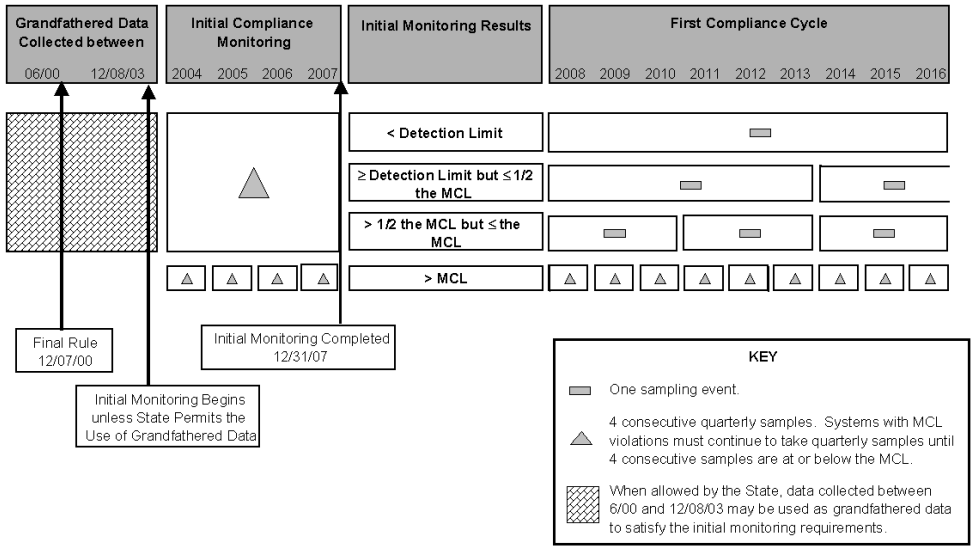
Grandfathering of Data

When allowed by the State, data collected between June, 2000 and December 8, 2003 may be used to satisfy the inital monitoring requirements if samples have been collected from:

- Each entry point to the distribution system (EPTDS).
- The distribution system, provided the system has a single EPTDS.
- The distribution system, provided the State makes a written justification explaining why the sample is representative of all EPTDS.

Applicability of the Standardized Monitoring Framework to Radionuclides

(Excluding the Beta Particle and Photon Emitters)



For additional information on the Radionuclides Rule

Call the Safe Drinking Water Hotline at 1-800-426-4791; visit the EPA Web site at http://water.epa.gov/drink.